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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/937,840 | 01/28/2002 | Patrick Soon-Shiong | ABI1550-1 | 7072 |
| 30542 | 7590 | 11/17/2004 | | |
| FOLEY & LARDNER P.O. BOX 80278 SAN DIEGO, CA 92138-0278 | | | | |
| EXAMINER DELACROIX MUIRHEI, CYBILLE | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1614 | | | | |

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,840

Applicant(s)

SOON-SHIONG ET AL.

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Detailed Action

The following is responsive to Applicant's amendment received Aug. 25, 2004.

Claim 6 is cancelled. No new claims are added. Claims 1-5, 7-21 are currently pending.

The previous claim objection and claim rejection under 35 USC 112, paragraph 1 set forth in paragraphs 1-3 of the office action mailed May 26, 2004 are **withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 102(b) over Regazzoni et al., set forth in paragraph 5 of the office action mailed May 26, 2004, is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 103(a) over Regazzoni et al. in view of WO '422, set forth in paragraph 7 of the office action mailed May 26, 2004, is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments concerning the previous claim rejection under 35 USC 102(b) over WO '422 and the previous claim rejection under 35 USC 103(a), set forth in paragraphs 4 and 6 of the office action mailed May 26, 2004, have been considered but are not found to be persuasive.

Said rejection is maintained essentially for the reasons given previously in the office action mailed May 26, 2004 with the following additional comment:

It is essentially Applicant's position that the claimed invention, as defined by claim 1, distinguishes over Wilson et al. by requiring treatment of a subject having cancer by administering to the subject a sub-therapeutic dose level of a

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pharmacologically active agent effective against the cancer, wherein the sub-therapeutic dose is administered over an extended administration time (e.g., in the range from about 7 days to about 1 year). Wilson et al. do not disclose or suggest such an administration protocol. In contrast, the "long term" administration of paclitaxel contemplated by Wilson et al. is no greater than 96 hours (barely half the minimum administration period of 7 days required by the present claims).

Said arguments have been carefully considered but are not found to be persuasive.

WO '422 discloses a method of administering for a long term, low doses of paclitaxel to a patient suffering from cancer (breast, lymphoma). The method specifically requires administering as a 96-hour continuous infusion a dose level of paclitaxel containing between 70 and 140 mg/M. The paclitaxel solution is delivered through a permanent central intravenous catheter, with cycles repeated every 21 days. Therefore the Examiner respectfully submits that the claims continue to be anticipated by WO '422.

With respect to the rejection under 35 USC 103(a) over WO '422, in addition to the reasons provided above, this rejection is also being maintained for reasons given previously in the office action mailed May 26, 2004.

Conclusion

Claims 1-21 stand rejected.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is 571-272-0572. The examiner can normally be reached on Mon through Thurs. from 8:30 to 6:00. The examiner can also be reached on alternate Fridays


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM



Nov. 15, 2004

